FAX

Telecopy/ Facsimile Transmission

Date: 10/27/05

Pages: 10 (Number of pages including this cover sheet)

TO: Mr. S. Kerber

(Attorney, Agent, Firm or Agency)

Docket #022731-0502 (Applicat^n #: 10/632,696)

(Attorney's Docket Number or Application Number)

8587926773

(FAX/Telecopier number)

The following is the text of a forthcoming communication in the above-captioned application

From: **Maryam Monshipouri** Ph.D., Examiner
Art Unit 1652

Technology Center 1600

Art Unit 1652 FAX Number:
Examiner's Office Number: (571) 272-0932

If you have not received all of the pages of this transmission, please contact the examiner at the office telephone number above.

All FAX machines will be available to receive transmissions 24 hours/ day, 7 days/ week.

In compliance with 1096 OG 30, the filing date accorded each official FAX transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or federal holiday within the District of Columbia, in which case the official date of receipt will be the next business day.

Mr. Kerber,

Please see the attached substitute restriction.

Thanks.

M.M.

Office Action Summary	Application No.	Applicant(s)	
	10/632,696	GLYNNE ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-68 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

On October 25th 2005 Mr. S. Kerber called the examiner to inquire about the restriction letter sent on 9/26/2005 wherein the claims did not match the instant application. In correction of said inadvertent error the examiner drafted a substitute restriction letter (see below) and reset the response due date starting from the date of faxing this restriction letter. **The previous due date, as indicated in the previous office action is hereby moot.**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16 and 18, drawn to isolated DNA sequences encoding CARD11 polypeptides, classified in class 435, subclass 194.

II. Claim 17, drawn to a method of inhibiting NFkB activity in a cell utilizing antisense oligonucleotides , classified in class 435, subclass 6.

III. Claim19, drawn to a method of inhibiting the degradation of RNA interference of a message in a cell utilizing RNA, classified in class 435, subclass 6.

IV. Claims 20-25, drawn to isolated CARD11 polypepitdes, classified in class 435, subclass 69.1.

V. Claims 26, 27 and 30, drawn to antibodies which specifically bind said CARD11 polypepitdes and methods of use of said antibodies, classified in class 435, subclass 7.1.

VI. Claims 28, drawn to a method of identifying a polypeitde having NFkB activating activity comprising utilizing agents that multimerize in the presence of said activating protein, classification unknown. This is

because classification depends on the chemical structure of said multimerizing agents and applicant has not specifically defined said agents.

VII. Claim 29, 33, drawn to methods of identifying a polypeitde having NFkB activity comprising contacting said CARD11 polypeptides with a promoter operatively linked to a reporter gene, classified in class 435, subclass 6.

VIII. Claim31, 32, 38, drawn to methods of identifying modulators of said NFkB activating polypeptides, classified in class 514, subclass 789.5.

IX. Claim 34, drawn to methods of detecting functional fragments of NFkB activating polypeptides utilizing said polypeptides, classified in class 435, subclass 69.1.

X. Claims 35-45, drawn to transgenic animals and their methods of sue, classified in class 800, subclass 8.

XI. Claims 46-50, drawn to knock-out non-human animals and methods of their use, classified in class 800 ,subclass 14.

XII. Claims 51-62, drawn to an inbred mouse comprising a genome that is homozygous for DNA encoding SEQ ID NO:2 and methods of its use, classified in class 800, subclass 18.

XIII. Claims 63-64, drawn to methods of generating toleragenic signals in a subject utilizing antisense DNA or antibodies, classified in class 435, subclass 6.

XIV. Claims 66-67, drawn to methods of tolerizing a subject to an antigen, utilizing antisense DNA or antibody or inhibitors, classified in class 435, subclass 6.

XV. Claim 68, drawn to a method of treatment utilizing modulators of NFkB activating activity, classified in class 514, subclass 789.5.

It should be noted that in addition to inventions listed as Groups I_XV above each invention is independently directed to the following two patentably distinct products of unrelated chemical structure and function:

(a) SEQ ID NO:1 and its truncated product SEQ ID NO:3

(b) SEQ ID NO:4

Applicant is advised to elect one invention from Groups I-XV and one invention from groups (a)-(b) in response to this office action.

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I, The polypeptides of Group IV, the antibodies of Group V, the transgenic animals of Group X, The knockout non-human animals of Group XI and the inbred mice of Group XII are patentably distinct each from the other because each invention is directed to a product of unrelated chemical structure an function.

The DNA of Group I is unrelated to any of the methods of Groups III, VI, VII, VIII, IX, and XV because said product is neither made not used by any of said methods.

Inventions I and II (or XIII or XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case antibodies may be used in said methods to inhibit NFkB activating function which are totally different products than antisense DNA of Group I.

The polypeptides of Group II are unrelated to any of the methods of Group II, III, VI, VII, XIII, and XIV because said products are neither made not used by any of said methods.

Inventions IV and VIII (or IX, or XV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group IV may be used in antibody preparation which is a totally different method than any of those e of Groups VIII, IX and XV.

The antibodies of Group V are unrelated to any of the methods of Groups II, III, VI,-IX, XIII-XV because said products are neither made not used in any of said methods.

The transgenic non-human animals of Group X, the knock-out non-human animals of Group XI, the inbred mice of Group XII are each unrelated to any of the methods of groups II, III, VI-IX and XIII-XV because non of said products are either made or used by any of said methods.

The methods of Groups II, III, VI-IX, and XIII-XV are patentably distinct each from the other because each method has different steps and different end-points.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or other wise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP section 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and he rejoined process will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, Thus, to be allowable, the rejoined clams must meet all the criteria for patentability including the requirement of 35 U.S.C. 101, 102, 103 and 112. Until an alerted product claims is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined, See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. section 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include limitations of the product claim. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP section 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 4:30 p.m. except for alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber Jon P. can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maryam Monshipouri Ph.D.

Primary Examiner

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